February 14, 2007

The Honorable Henry Waxman
United States House of Representatives
Washington, DC 20515

Dear Representative Waxman:

The Generic Pharmaceutical Association (GPhA) is pleased to endorse the "Access to Life Saving Medicine Act" ("ALSMA"). We thank you for your leadership efforts in working to bring safe, effective and affordable biogenerics to consumers and for making an important contribution toward constraining unsustainable pharmaceutical cost growth for businesses, labor organizations, and health plans as well federal, state and local governments.

For those who suffer from life-threatening diseases and chronic illnesses, biopharmaceuticals provide great hope for quality care and long-term treatment. Yet, without generic versions of these medicines, countless Americans will be unable to share the hope these medicines provide. By creating a safe, clear and efficient abbreviated approval pathway, the legislation that you and your bipartisan colleagues are introducing today will help save consumers and our health care system billions of dollars and will bring the true promise of these life-saving medicines to patients in need.

Biopharmaceuticals are the fastest growing sector of prescription drug expenditures in the United States. The market for these medicines is growing at an annual rate of 20 percent—and the per-patient costs are growing as well. Costs can run anywhere from $10,000 to $200,000 per patient per year. For example, treatment with the colon cancer drug Avastin costs $100,000 per year—that's more than double the median American annual income. Even a 10 percent to 25 percent reduction in biopharmaceutical costs could amount to billions of dollars in savings to consumers. Indeed, according to a study by Express Scripts, biogenerics could save Americans more than $71 billion over ten years. In this regard, a study released by the Pharmaceutical Care Management Association revealed that biogenerics would save Medicare's inpatient pharmaceutical program alone $14 billion over ten years. That is clearly just the tip of the potential savings as this projection does not include all of Medicare's covered outpatient prescriptions, Medicaid or the Department of Veterans Affairs.

ALSMA sets forth a clear, efficient abbreviated pathway in order to bring safe, effective and affordable biogenerics to consumers. Without such a pathway, millions of Americans will be unable to obtain the medicines they need at a price they can afford. This science-based, clear and efficient pathway will ensure safety and efficacy by providing FDA with the authority and flexibility it needs to request necessary data and tests on a product-by-product basis. Safety is and always will be a paramount concern of the generic industry. With over twenty years of experience and scientific advances, FDA now has even more sophisticated scientific tools to ensure safety and efficacy than it did when it first approved the parent biopharmaceuticals that are coming off patent.

ALSMA also makes great strides in preserving patient access by calling for timely resolution of patent disputes. Biogenerics will only truly be life-saving treatments if they are able to reach the market. Congress must therefore ensure that needless barriers to consumer access are eliminated so that the true promise of biogenerics can be achieved.

For more than twenty years, generic medicines have been improving lives for less. It is time for Congress to make certain that FDA creates a clear and efficient abbreviated approval pathway for biogenerics. Only then will biogenerics be able to begin to start improving the lives of millions of Americans who currently cannot afford the high costs of brand biopharmaceuticals.

Thank you again for your leadership. We look forward to working with you to pass and enact this critical, broadly supported and bipartisan legislation in this session of Congress.

Sincerely,

Kathleen Jaeger
President and CEO

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